

PATENT COOPERATION TREATY

AY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1581/140 WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US04/05602	International filing date (day/month/year) 26 February 2004 (26.02.2004)	Priority date (day/month/year) 26 February 2003 (26.02.2003)
International Patent Classification (IPC) or national classification and IPC IPC: A61F 13/00(2006.01),13/02(2006.01);A61L 15/16(2006.01);A61K 9/70(2006.01) USPC: 424/448,449		
Applicant LA VIPHARM S.A.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>0</u> sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input checked="" type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand 26 January 2005 (26.01.2005)	Date of completion of this report 20 May 2008 (20.05.2008)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Michael Woodward <i>J. Roberts for</i> Telephone No. 571-272-1600	

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US04/05602

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-23 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____.
- ☒ the claims:
pages 24-33 as originally filed
pages NONE as amended (together with any statement) under Article 19
pages NONE filed with the demand
pages NONE filed with the letter of _____.
- ☒ the drawings:
pages 1-5 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____.
- ☐ the sequence listing part of the description:
pages NONE as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US04/05602

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 37, 58 and 70-81

because:

- ☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require international preliminary examination (*specify*):

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 58 are so unclear that no meaningful opinion could be formed (*specify*):

Please See Continuation Sheet

- ☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. 37 and 70-81

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US04/05602

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)

Claims Please See Continuation Sheet YES

Claims Please See Continuation Sheet NO

Inventive Step (IS)

Claims Please See Continuation Sheet YES

Claims Please See Continuation Sheet NO

Industrial Applicability (IA)

Claims Please See Continuation Sheet YES

Claims Please See Continuation Sheet NO

2. CITATIONS AND EXPLANATIONS

Please See Continuation Sheet

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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(PCT Article 36 and Rule 70)

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Applicant LA VIPHARM S.A.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>8</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>0</u> sheets.</p>		
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Date of submission of the demand 26 January 2005 (26.01.2005)	Date of completion of this report 20 May 2008 (20.05.2008)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Michael Woodward <i>J. Roberts for</i> Telephone No. 571-272-1600	

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US04/05602

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- ☒ the description:
pages 1-23 _____ as originally filed
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pages NONE _____, filed with the letter of _____.
- ☒ the claims:
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pages NONE _____, as amended (together with any statement) under Article 19
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☒ the drawings:
pages 1-5 _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.
- ☐ the sequence listing part of the description:
pages NONE _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____.

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- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

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- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US04/05602

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 37, 58 and 70-81

because:

- ☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require international preliminary examination (*specify*):

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 58 are so unclear that no meaningful opinion could be formed (*specify*):

Please See Continuation Sheet

- ☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.
☒ no international search report has been established for said claims Nos. 37 and 70-81

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US04/05602**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)

Claims Please See Continuation Sheet YESClaims Please See Continuation Sheet NO

Inventive Step (IS)

Claims Please See Continuation Sheet YESClaims Please See Continuation Sheet NO

Industrial Applicability (IA)

Claims Please See Continuation Sheet YESClaims Please See Continuation Sheet NO**2. CITATIONS AND EXPLANATIONS**

Please See Continuation Sheet

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US04/05602

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claim 6 is objected to as lacking clarity under PCT Rule 66.2(a)(v) because the claim 6 is not fully supported by the description.

The application, as originally filed, did not describe: the step of attaching a second release liner occurs before the step of attaching the barrier layer.

Claims 30, 31 and 50 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claim is indefinite for the following reason(s):

The term "high specific" in claim 30 is a relative term which renders the claim indefinite. The term "high specific" is not defined by the claim, the description does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what applicant considers a high specific surface area to be. Please clarify.

Claim 31 is indefinite due to its dependency.

Claim 58 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claim is indefinite for the following reason(s):

With respect to claim 58, independent claim 38 recites the first release liner is in "direct contact" with the active layer, covering a side of the active layer, and claims 56 and 57 recite a barrier layer is attached to the active layer with an adhesive, where the barrier layer is disposed on an opposite side of the active layer from the first release liner. From this claim language, it appears the active layer is sandwiched between a first release liner and a barrier layer. However, claim 58 recites the first release liner is attached to the barrier layer. From the claim language, it appears the layering is active layer - adhesive - barrier layer - release liner. If this is the situation, it is unclear how the first active release liner is in "direct contact" with the active layer, as recited in claim 38, if it is attached to the barrier layer. Please clarify. The scope of the claim is so unclear that it cannot be treated on the merits.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Section III. Non-establishment of report (description/claims/drawings unclear)

Claim 58 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claim is indefinite for the following reason(s):

Claims 38 recites the first release liner is in "direct contact" with the active layer, covering a side of the active layer, and claims 56 and 57 recite a barrier layer is attached to the active layer with an adhesive, where the barrier layer is disposed on an opposite side of the active layer from the first release liner. From this claim language, it appears the active layer is sandwiched between a first release liner and a barrier layer. However, claim 58 recites the first release liner is attached to the barrier layer. From the claim language, it appears the layering is active layer - adhesive - barrier layer - release liner. If this is the situation, it is unclear how the first active release liner is in "direct contact" with the active layer, as recited in claim 38, if it is attached to the barrier layer. Please clarify. The scope of the claim is so unclear that it cannot be treated on the merits.

V. 1. Reasoned Statements:

The opinion as to Novelty was positive (Yes) with respect to claims 5-18, 21, 25, 30, 31, 35, 41, 45, 50, 54 and 60-67

The opinion as to Novelty was negative (No) with respect to claims 1-4, 19, 20, 22-24, 26-29, 32-34, 36, 38-40, 42-44, 46-49, 51-53, 55-57, 59, 68 and 69

The opinion as to Inventive Step was positive (Yes) with respect to claims 6-18, 30, 31, 50 and 60-66

The opinion as to Inventive Step was negative (NO) with respect to claims 1-5, 19-29, 32-34-36, 38-44, 46-49, 51-57, 59 and 67-69

The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-36, 38-57 and 59-69

The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE

V. 2. Citations and Explanations:

Claims 1, 2, 4, 19, 20, 23, 24, 32-34, 38-40, 43 and 44 lack novelty under PCT Article 33(2) as being anticipated by Ebert et al. (US 5,626,866)

With respect to claim 1, Ebert et al. discloses a method for making an active layer to deliver a volatile substance, the method comprising providing a polymer solution including a polymer, a solvent, and the volatile substance, applying the polymer solution to a side of a first release liner, and drying the polymer solution to create the active layer (Examples 2 and 6)

With respect to claim 2, Ebert et al. discloses positioning a barrier layer (backing layer) disposed on an opposite side of the active layer from the first release liner.

With respect to claim 4, Ebert et al. discloses using the method of making an active layer in formulating nicotine-containing patches (abstract).

With respect to claims 19, 20, 39 and 40, Ebert et al. discloses the polymer solution is a polyurethane (col. 8, lines 52-66).

With respect to claims 23, 24, 43 and 44, Ebert et al. discloses the inclusion of a thickener (HPC) (Example 6).

With respect to claims 32-34 and 51-53, Ebert et al. discloses the active layer is a rate controlling active layer that includes a rate controlling composition that controls the rate of delivery of the volatile substance, and the rate controlling composition includes another polymer (ethylenevinyl acetate copolymer) (col. 8, lines 30-66).

With respect to claim 38, Ebert et al. discloses in Fig. 1, a device for delivering a volatile substance comprising an active layer (18), the active layer being a dried polymer solution having the volatile substance, and a first release liner (22) in direct contact with the active layer, and covering a side of the active layer.

Claims 21, 25, 35, 41, 45 and 54 lack an inventive step under PCT Article 33(3) as being obvious over Ebert et al.

With respect to claims 21 and 41, Ebert et al. addresses all the limitations of claims 20 and 40, however fails to expressly

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US04/05602**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

disclose the type of polyurethane used. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the type of polyurethane used, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

With respect to claims 25 and 45, Ebert et al. addresses all the limitations of claims 23 and 43, however fails to expressly disclose using the claimed thickeners. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the type of thickener used, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

With respect to claims 35 and 54, Ebert et al. addresses all the limitations of claims 32 and 51, however fails to expressly disclose using the claimed materials in the rate controlling composition. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the materials used in the rate controlling composition, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 1-4, 22, 26-29, 32-34, 36, 38, 42, 46-49, 51-53, 55-57, 59, 68 and 69 lack novelty under PCT Article 33(2) as being anticipated by DiSapio et al. (US 4,874,129).

With respect to claim 1, DiSapio et al. discloses in Figs. 1 and 7, a method for making an active layer to deliver a volatile substance, the method comprising providing a polymer solution including a polymer, a solvent, and the volatile substance (perfume), applying the polymer solution to a side of a first release liner (10C), and drying the polymer solution to create the active layer (col. 6, lines 18-26; col. 13, lines 1-3).

With respect to claims 2, 4 and 69, DiSapio et al. discloses positioning a barrier layer (10A) disposed on an opposite side of the active layer from the first release liner.

With respect to claim 3, DiSapio et al. discloses in Fig. 7, attaching the barrier layer (70A) to the opposite side of the active layer (70B) from the first release liner (70C) by a first adhesive layer (70D).

With respect to claims 22 and 42, DiSapio et al. discloses the volatile substance is a perfume (col. 6, lines 10-13).

With respect to claims 26-28 and 46-48, DiSapio et al. discloses the polymer solution comprises glycol (col. 6, lines 63-65).

With respect to claim 29, and 49, DiSapio et al. discloses the active layer is a solid (pressure sensitive adhesive) (col. 6, lines 18-19).

With respect to claims 32-34, 36, 51-53 and 55, DiSapio et al. discloses the active layer is a rate controlling active layer that includes a rate controlling composition that controls the rate of delivery of the volatile substance, wherein the rate controlling composition includes polyester (Mylar backing) (col. 13, lines 1-2, 35).

With respect to claim 38, DiSapio et al. discloses in Figs. 1 and 7, a device for delivering a volatile substance comprising an active layer (10B), the active layer being a dried polymer solution having the volatile substance, and a first release liner (10C) in direct contact with the active layer, and covering a side of the active layer.

With respect to claim 56, DiSapio et al. discloses in Fig. 1, a barrier layer (10A) disposed on an opposite side of the active layer from the first release liner.

With respect to claim 57 and 59, DiSapio et al. discloses in Fig. 7, a barrier layer (10A) disposed on an opposite side of the active layer from the first release liner, wherein the barrier layer is attached to the active layer with an adhesive (7D).

With respect to claim 68, Fig. 7 illustrates the active layer is attached to an adhesive, thereby having an adhesive property.

Claims 5 and 67 lacks an inventive step under PCT Article 33(3) as being obvious over DiSapio in view of Fischel-Ghodsian.

With respect to claim 67, DiSapio et al. addresses all the limitations of claims 38 and 56, however fails to expressly disclose a second release liner attached to an opposite side of the barrier layer from the active layer. Fischel-Ghodsian teaches using a second release liner on an opposite side of a barrier layer from the active layer (col. 9, lines 46-50). It would have been obvious to one of ordinary skill in the art to include a second release liner for packaging and storage purposes, as taught by Fischel-Ghodsian.

Claims 35 and 54 lack an inventive step under PCT Article 33(3) as being obvious over DiSapio et al.

With respect to claims 35 and 54, DiSapio et al. addresses all the limitations of claims 32 and 51, however fails to expressly disclose using the claimed materials in the rate controlling composition. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the materials used in the rate controlling composition, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 6 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the step of attaching a second release liner occurs before the step of attaching the barrier layer.

Claim 7 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the barrier layer is a double coated tape, each side of the double coated tape covered by an adhesive layer, and wherein position includes attaching

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US04/05602

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

the double coated tape to the opposite side of the active layer from the first release liner by one of the adhesive layers of the double coated tape.

Claims 8-18 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest applying a fractional adhesion layer to an opposite side of the barrier layer from the active layer.

Claims 30 and 31 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the polymer solution is applied to create a surface with a high specific surface area.

Claim 50 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a side of the active layer adjacent the first release liner has a higher specific surface area than a smooth surface.

Claims 60-66 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a mask layer covering at least a portion of the barrier layer, and adhesive adjacent to an opposite side of the mask layer from the barrier layer, the adhesive covering an area that is only a fraction of a total area of a side of the barrier layer.

Claims 1-36, 38-57 and 59-69 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in cosmetic industry.

----- NEW CITATIONS -----

US 5,626,866 A (EBERT et al) 06 May 1997 (06.05.1997), Examples 2, 6; abstract; col. 8, lines 30-66; Fig. 1.

US 4,874,129 (DISAPIO et al) 17 October 1989 (17.10.1997), col. 6, lines 10-13, 18-26, 63-65; col. 13, lines 1-3, 35; Figs. 1 and 7.

US 5,071,704 (FISCHEL-GHODSIAN) 10 December 1991 (10.12.1991), col. 9, lines 46-50.